

**Translation**

**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>443449EH</b>	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. <b>PCT/EP2004/009536</b>	International filing date (day/month/year) <b>26.08.2004</b>	Priority date (day/month/year) <b>29.08.2003</b>
International Patent Classification (IPC) or national classification and IPC <b>A61K7/48, A61K33/38</b>		
Applicant <b>BIO-GATE AG.</b>		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☒ (sent to the applicant and to the International Bureau) a total of 1 sheets, as follows:

☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/009536

Box No. 1 Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-17 \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the claims:
- nos. 2-14, 17-31 \_\_\_\_\_ as originally filed/furnished
- nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19
- nos.\* 1, 15, 16 received by this Authority on 09.06.2005 with letter
- nos.\* \_\_\_\_\_ received by this Authority on of 07.06.2005
- ☒ the drawings:
- sheets 1/2, 2/2 \_\_\_\_\_ as originally filed/furnished
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability:  
citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1-31	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-31	NO
Industrial applicability (IA)	Claims	1-31	YES
	Claims		NO

## 2. Citations and explanations (Rule 70.7)

## 1. Reference is made to the following documents:

D1: WO 02/17984 A (STEINRUECKE PETER; BECHERT  
THORSTEN (DE); BIO GATE BIOINNOVATIVE MATE),  
7 March 2002 (2002-03-07)

D2: US-A-5 595 750 (JACOBSON HOWARD W ET AL),  
21 January 1997 (1997-01-21)

D3: US-A-4 828 832 (DE CUELLAR BLANCA ROSA A ET AL),  
9 May 1989 (1989-05-09)

D4: US-A-4 906 466 (PRATT ALLIN S ET AL),  
6 March 1990 (1990-03-06)

The amendments submitted with the letter of 7 June 2005  
do not introduce any material that violates the  
requirement of PCT Article 34(2)(b) by going beyond the  
disclosure in the international application as filed.

2. Novelty (PCT Article 33(2))

The subject matter of claims 1 to 31 is novel (PCT  
Article 33(2)).

Document D1 discloses an antimicrobial material

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Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability:  
citations and explanations supporting such statement

for implantation in bones, or for coating or manufacturing an implant or an implantable medical device, comprising finely dispersed particles of an antimicrobial metal in a material that forms a matrix in its cured state. According to the invention, the metal is formed of aggregates of primary particles with an average grain size between 10 and 100 nm. In an advantageous embodiment the aggregates have an average grain size between 1 and 20  $\mu\text{m}$ , preferably between 10 and 20  $\mu\text{m}$ . They can have a porosity of 70% to 95%. These features help ensure a uniform and cytotoxically safe release of silver ions at the surface of the material (see the whole of D1). D1 does not disclose a body care product for application to skin and/or mucous membranes.

Document D2 discloses an antimicrobial mixture containing particles of a core material formed from a metal oxide, a sulphate, a sulphide, a zeolite, mica, talc, kaolin, silica or mullite (see D2, column 1, lines 12 to 26; column 2, lines 33 to 55; column 3, line 60 to column 4, line 16; column 5, lines 2 to 55; column 10, line 39 to column 11, line 27; also examples 1 to 11). D2 does not disclose a body care product containing metallic silver for application to skin and/or mucous membranes.

Document D3 discloses a body care product containing metallic silver particles with an average diameter between 1 and 10  $\mu\text{m}$  (see D3, column 2, line 57 to column 3, line 65; also claims 1 to 13). The metallic particles in D3 are not porous.

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Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
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Document D4 discloses a body care product containing metallic silver particles with an average diameter between 1 and 15  $\mu\text{m}$  (see D4, column 1, lines 23 to 36; column 2, lines 38 to 46; column 3, lines 6 to 54; column 4, lines 1 to 40; also claims 1 to 7). The metallic particles in D4 are not porous.

3. Inventive step (PCT Article 33(3))

Claims 1 to 31 cannot be considered inventive (PCT Article 33(1) and (3)).

The problem addressed by the present invention is that of providing an antimicrobial body care product that does not have the drawbacks associated with silver nanoparticles.

The problem is solved by the claimed body care product for application to skin and/or mucous membranes, which contains porous metallic particles that contain metallic silver and have an average diameter between 1 and 100  $\mu\text{m}$ .

Document D3, which is considered to be the closest prior art, describes a body care product containing metallic silver particles with an average diameter between 1 and 10  $\mu\text{m}$  (see D3, column 2, line 57 to column 3, line 65; also claims 1 to 13).

The difference between D3 and the present invention is essentially the fact that the metallic particles are porous.

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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This feature is just one of a number of obvious possibilities from which a person skilled in the art would choose according to the circumstances in order to solve the problem of interest, without making an inventive contribution. The subject matter of claims 1 to 31 therefore does not involve an inventive step and thus fails to meet the requirement of PCT Article 33(1) and (3).

4. Industrial applicability (PCT Article 33(4))

The subject matter of claims 1 to 31 is industrially applicable (PCT Article 33(4)).